



Current Issues for CLIA Categorization

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***The Division of Clinical Laboratory Devices
and the CLIA Categorization Team proudly***

***announces the selection of Dr. Bernard
Statland as CDRH's new Office Director. Dr.
Statland is an alumnus of the Clinical
Pathology Service at NIH's Clinical Center.***

Dr. Statland knows IVDs!

Current Issues for CLIA Categorization

Present

- Current process at the FDA
- CDC and HCFA roles
- CLIA Accomplishments

Current Issues for CLIA Categorization

Present

- Impact on Manufacturers
- Impact on Laboratories
- Other CLIA News

Current Issues for CLIA Categorization

Future

- Public Meeting
 - Purpose
 - Input
 - Options
- Path Forward

Supporting Roles

- HCF A - notify them of waived products
provide copy of cleared, approved package insert
- CDC - consultation with FDA particularly on waived applications
- FDA keeps both apprised of new technology

Accomplishments

Since January 14, 2000

>520 devices categorized

510(k), PMA, HDE

>450 moderate, high categorizations performed

76% = moderate

23% = high

Accomplishments

>72 waived

1% = waived

> only 2(72) waived using 9/13/95 waiver criteria

>Princeton Biomed iTech Strep A

>LifeSign Strep A

OT C, Prescription Home Use

OT C Standard, Substantial Equivalence

- Benefits must outweigh risks in the hands of lay users
- Truth in labeling; imperfect tests labeled with caution

Route to Waiver

Majority

- OTC, prescription home use
- Professional use versions of the above
- Generic 9
- Relabeling of all of the above

Minority

- Waiver Criteria

OTC, Prescription Home Use

>The OTC standard is based on
Substantial Equivalence

- Benefits must outweigh risks in hands of lay users;
- Truth in labeling; imperfect tests are labeled with caution

Professional Use Version

- Test has been cleared, approved for OTC, prescription home use
- FDA reviews the QC of professional use version; waives if appropriate
- Example of Professional Use version of Prescription Home Use test--Avocet Prothrombin Time

Impact on Manufacturers

- Streamlined administrative processes
- One stop agency for marketing and categorization, CDRH & CBER
- Reviewer familiar with the products
- Categorization, no impediment to clearance or approval
- Improved turn around time, decision

Impact on Laboratories

- Improved turnaround time for categorization notification

Access to FDA's

- Releaseable 510(k) database
- Releaseable Premarket Approval Database

Other CLIA News

- Appeals for waiver may be processed in a manner similar to device appeals
- Publication of the Administrative guidance for submitting categorizations to the FDA is imminent as a Level 1
- Guidance for waiver on hold until after public meeting

Other CLIA News

- Routine CLIA categorizations are performed in conjunction with FDA review
- Optimally, the categorization should accompany SE or be sent shortly after
- Last CLIA hire should come on board this month
- CLIA website posting of categorizations summer 2000

Public Meeting

- Meeting to be held in Washington DC area
- Aug 14-15, 2000
- FDA to discuss proposed waiver criteria with stakeholders

Public Meeting (cont..)

Purpose

- Additional comments on criteria and process
- FDA needs to decide how to apply criteria
- Effectively implement new responsibilities of CLIA

Public Meeting (cont..)

FDA needs stakeholder input

- Notice of public hearing
- Notice of participation
- If you wish to participate, FDA will allot time based on number of presenters

Public Meeting (cont....)

Type of Input

- Submit your model for waiver
--quantitative, qualitative tests
- Post on Dockets Management web site before meeting
- FDA allows for comments 30 days after hearing

Options

- > Findize current rule
- > Repropose rule
- > Go to negotiated rulemaking
- > Others

Discussion Points

- Must the test be more accurate than those performed in the laboratory?
- Or is it adequate that tests run by untrained users receive the same results as those performed in the laboratory?

Focus on the Operator

- FDAMA modifies the PHS Act to clarify that waived tests include those which employ methodologies that are so "simple" and "accurate" as to render the likelihood of erroneous results by the user negligible

Focus on the Operator

- Is the untrained user able to reproduce the results obtained by the laboratory?

Focus on the Product

- Another interpretation “erroneous results” and “accurate” include the inherent clinical sensitivity and specificity of a test
- Waiver test must be compared to reference methods, materials and show no statistically significant difference between the two.

Waiver Process

Scope

- FDA, the point of entry
- Collaboration with CDC
- FDA following the same policies that CDC applied before the transfer
- Conservative standards based approach
- “Damn Near Perfect” (DNP) coined by Steve Gutman in January 2000

Scope

FDA's interpretation of accuracy

- Use of reference methods, materials
- Use of target values for inherent clinical sensitivity and specificity

Scope

- FDA continues to meet with manufacturers
- FDA following criteria established by CDC
- FDA's future goal - simultaneous FDA and CLIA waiver review

Comments: Notice of Proposed Rulemaking Sept 13, 1995

- Majority agreed OTC = waived
- Take the "Improvement" out of CLIA
- POLs have improved; let the process continue
- CLO tests should be waived

Comments NPRM

- Negative impact on business of laboratory medicine
- Increasing profits by freedom of sale of unregulated products
- No quantitative tests for waiver
- Specific comments on waiver criteria

Comments NPRM

- Allow simple processing of specimens
- Minimal specimen manipulation
- Remove the term fail-safe, implies full protection from malfunction; waived "essentially error free."
- Minimal electronic or mechanical maintenance

Comments NPRM

- Define which interfering substances are of concern
- Delete “reagent impregnated device”; not all qualitative waived tests contain impregnated reagents
- Delete “report to PHS any performance problems not resolved by manufacturer”

Statistics for Quantitative Tests

- Tonks rule of thumb never intended as performance standard
- Does not account for variety of intended clinical uses for individual analytes

Path Forward

- Finalize the rule for waiver criteria and process
- Add tests not currently regulated
- Waiver tests on the rise
- Manufacturers designing products for waiver
- Increased regulation for waived?
- Limit the types of tests eligible for waiver?